

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No. : PCT/US2004/009620
International Filing Date : 29 March 2004 (29.03.2004)
Earliest Priority Date : 28 March 2003 (28.03.2003)
Applicant(s) : C.R. BARD, INC. ET AL.
Title : METHOD AND APPARATUS FOR SELECTING
OPERATING PARAMETER VALUES IN
ELECTROPHYSIOLOGY PROCEDURES

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing a Demand for International Preliminary Examination,
Response to Written Opinion and Fee Calculation Sheet with Deposit Account Authorization.

A check in the amount of \$912.00 is enclosed to cover the fee. If this is insufficient, please
charge any deficiency, or credit any overpayment in the total fees, to the account of Wolf,
Greenfield & Sacks, P.C., Deposit Account No. 23/2825.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application
Branch is respectfully requested to contact the undersigned collect at (617) 646-8000, Boston,
Massachusetts.

Respectfully submitted,



Eric Amundsen
Reg. No.: 46,518
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 646-8000
Facsimile: (617) 646-8646

DOCKET NO.: B1075.71016

DATE: 28 January 2005

x 1/28/05

Express Mail Label No.: EL960700835US

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of the Authority may be indicated by the applicant on the line below:

IPEA/US

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty

For International Preliminary Examining Authority use only

Identification of IPEA

Date of Receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference
B1075.71016

International Application No.
PCT/US2004/009620

International Filing Date (day/month/year)
29 March 2004 (29.03.2004)

(Earliest) Priority date (day/month/year)
28 March 2003 (28.03.2003)

Title of Invention
METHOD AND APPARATUS FOR SELECTING OPERATING PARAMETER VALUES IN ELECTROPHYSIOLOGY PROCEDURES

Box No. II APPLICANT(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

C.R. BARD, INC.

730 Central Avenue

Murray Hill, New Jersey 07974

United States of America

Telephone No.:

Facsimile No.:

Teleprinter No.:

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

STEVENS-WRIGHT, Debbie

175 Candlestick Road

North Andover, Massachusetts 01845

United States of America

State (that is, country) of nationality:
US

State (that is, country) of residence:
US

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

State (that is, country) of nationality:

State (that is, country) of residence:

☐ Further applicants are indicated on a continuation sheet.

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCEThe following person is ☒ agent ☐ common representative

And ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.
☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Attorney, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

AMUNDSEN, Eric.
 Wolf, Greenfield & Sacks, P.C.
 600 Atlantic Avenue
 Boston, Massachusetts 02210
 United States of America

Telephone No.:
(617) 720-3500Facsimile No.:
(617) 720-2441

Teleprinter No.:

☐ **Address for Correspondence:** Mark this check box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION**Statement concerning amendments:***

1. The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filed to include the Rectification of Obvious Errors as filed on 01 July 2004

the description ☐ as originally filed
☐ as amended under Article 34

the claims ☐ as originally filed
☐ as amended under Article 19 (together with any accompanying statement)
☐ as amended under Article 34

the drawings ☐ as originally filed
☐ as amended under Article 34

2. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of the applicable time limit under Rule 69.1(d).4. ☐ The applicant wishes the start of the international preliminary examination to start earlier than the expiration of the applicable time limit under Rule 69.1(d).

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: . . . English

- ☒ which is the language in which the international application was filed.
☐ which is the language of a translation furnished for the purposes of international search.
☐ which is the language of publication of the international application
☐ which is the language of the translation to be furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The filing of this demand constitutes the election of all Contracting States which are designated and are bound by Chapter II of the PCT.

Box No. VI CHECKLIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- | | | | | |
|----|---|---|---|--------|
| 1. | translation of international application | : | | sheets |
| 2. | amendments under Article 34 | : | | sheets |
| 3. | copy (or, where required, translation) of amendments under Article 19 | : | | sheets |
| 4. | copy (or, where required, translation) of statement under Article 19 | : | | sheets |
| 5. | letter | : | 4 | sheets |
| 6. | other (<i>specify</i>) | : | | sheets |

For International Preliminary Examining Authority use only

Received not received

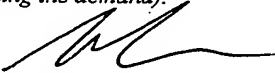
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| <input type="checkbox"/> | <input type="checkbox"/> |

The demand is also accompanied by the item(s) marked below:

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> fee calculation sheet | 4. <input type="checkbox"/> statement explaining lack of signature |
| 2. <input type="checkbox"/> separate signed power of attorney | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input checked="" type="checkbox"/> other (<i>specify</i>):
Transmittal letter
Postcard
Check |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).



AMUNDSEN, Eric

For International Preliminary Examining Authority use only

- | | |
|--|---|
| 1. Date of actual receipt of DEMAND: | |
| 2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b): | |
| 3. <input type="checkbox"/> The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. | <input type="checkbox"/> The applicant has been informed accordingly. |
| 4. <input type="checkbox"/> The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5. | |
| 5. <input type="checkbox"/> Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82. | |
| 6. <input type="checkbox"/> The date of receipt of the demand is AFTER the expiration of the time limit under Rule 54bis.1(a) and item 7 or 8 below, does not apply. | |
| 7. <input type="checkbox"/> The date of receipt of the demand is WITHIN the time limit under Rule 54bis.1(a) as extended by virtue of Rule 80.5. | |
| 8. <input type="checkbox"/> Although the date of receipt of the demand is after the expiration of the time limit under Rule 54Bis.1(a), the delay in arrival is EXCUSED pursuant to Rule 82. | |

For International Bureau use only

Demand received from IPEA on:

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

For International Preliminary Examining Authority use only

International Application No. PCT/US2004/009620		Date stamp of the IPEA
Applicant's or agent's File reference: B1075.71016		
Applicant C.R. BARD, INC. ET AL.		
Calculation of prescribed fees		
1. Preliminary examination fee	\$750.00 (USPTO was not ISA)	P
2. Handling fee	\$162.00	H
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box	\$912.00	
TOTAL		
Mode of Payment		
<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> authorization to charge deposit account with the IPEA (see below) </div> <div> <input type="checkbox"/> cash </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div> <input checked="" type="checkbox"/> cheque </div> <div> <input type="checkbox"/> revenue stamps </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div> <input type="checkbox"/> postal money order </div> <div> <input type="checkbox"/> coupons </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div> <input type="checkbox"/> bank draft </div> <div> <input type="checkbox"/> other (specify): </div> </div>		
Deposit Account Authorization (this mode of payment may not be available at all IPEAs) The IPEA/US <input type="checkbox"/> is hereby authorized to charge the total fees indicated above to my deposit account. <input checked="" type="checkbox"/> (this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.		
23/2825	28/1/2005	
Deposit Account Number		AMUNDSEN, Eric
Form PCT/IPEA/401 (Annex) (July 1998; reprint January 2000)		
See notes to the fee calculation sheet		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AS INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International Application No.: PCT/US2004/009620
International Filing Date: 29 March 2004 (29.03.2004)
Earliest Priority Date: 28 March 2003 (28.03.2003)
Applicant(s): C.R. BARD, INC. ET AL.
Title: METHOD AND APPARATUS FOR SELECTING
OPERATING PARAMETER VALUES IN
ELECTROPHYSIOLOGY PROCEDURES

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO WRITTEN OPINION

In response to the Written Opinion mailed 25 August 2004 (25.08.2004), Applicant respectfully requests reconsideration of the above-identified application by the International Preliminary Examining Authority in view of the following remarks and amendments.

Claims 1-90 are pending in the application. No claims have been amended. No claims have been canceled. No claims have been added.

REMARKS

Applicant acknowledges and appreciates the Examiner's finding that claims 1-29, 34, and 35 meet the requirements of the PCT with respect to novelty, inventive step and industrial applicability.

In response to Paragraph III.1 of the Written Opinion, Applicant would like to point out that each independent claim is distinct and each independent claim also is clear and concise. While the application is directed generally to apparatuses and methods for selecting values for operating parameters to be used in systems and apparatuses configured to create lesions in heart tissue, each independent claim is distinct. Several of the independent claims are directed to establishing a relationship between operating condition values and values for ablation operating parameters.

Claim 1 is directed to a method of selecting an operating parameter value for supplying energy to an ablation electrode. The method comprises receiving a first signal representing a value of a fluid flow rate, receiving a second signal representing a value of an

impedance, receiving a third signal representing a value of a distance from an ablation electrode surface to a target tissue surface, and selecting a value for an operating parameter for supplying energy to the ablation electrode as a function of the first, second and third signals.

Claim 31 is directed to a method of ablating biological tissue to form a lesion. The method comprises positioning an ablation electrode having a surface at an ablation site, receiving a first signal representing a value of a fluid flow rate, receiving a second signal representing a value of an impedance, receiving a third signal representing a value of a distance from the ablation electrode surface to a target tissue surface, selecting a value for an ablation operating parameter as a function of the first, second and third signals, and operating the ablation electrode at the selected operating parameter value to ablate biological tissue.

Claim 34 is directed to a system which comprises a catheter having a shaft, an ablation electrode positioned on the shaft, an energy supply, and an input interface. The input interface is configured to receive a signal representing a value of a fluid flow rate, a signal representing a value of an impedance, and a signal representing a value of a distance from an electrode surface to a target tissue surface. The system also comprises a processor operatively connected to the input interface and programmed to select an operating parameter value for supplying energy to the ablation electrode with the energy supply, the selection being a function of the three signals received by the input interface, and an output interface operatively connected to the processor and configured to provide the selected operating parameter value.

Claim 35 is directed to a computer-readable medium which has instructions stored thereon that, as a result of being executed by a computer, instruct the computer to perform a method comprising receiving a first signal representing a value of a fluid flow rate, receiving a second signal representing a value of an impedance, receiving a third signal representing a value of a distance from an ablation electrode surface to a target tissue surface, and selecting a value for an operating parameter for supplying energy to the ablation electrode as a function of the first, second and third signals.

Claim 36 is directed to a system which comprises a catheter having a shaft, an ablation electrode positioned on the shaft, an energy supply, and an input interface. The input interface is configured to receive a first signal representing a value of a fluid flow rate, a second signal representing a value of an impedance, and a third signal representing a value of a distance from an electrode surface to a target tissue surface. The system further comprises means for selecting an operating parameter value for supplying energy to the ablation

electrode with the energy supply, the means for selecting using the first, second and third signals, and an output interface configured to provide the selected operating parameter value.

Claim 38 is directed to a method of selecting an operating parameter value for transmitting energy to tissue. The method comprises receiving a first signal representing a value of a fluid flow rate near the tissue, receiving a second signal representing a value of an impedance, and selecting a value for a distance to set an ablation electrode surface apart from a target tissue surface as a function of the first and second signals.

Claim 44 is directed to a method of selecting an operating parameter value for transmitting energy to tissue. The method comprises receiving a first signal representing a value of a fluid flow rate near the tissue, and selecting a value for a distance to set an ablation electrode surface apart from a target tissue surface as a function of the first signal.

Claim 56 is directed to a method of selecting an operating parameter value for supplying energy to an ablation electrode. The method comprises receiving a first signal representing a value of a fluid flow rate near the tissue, receiving a second signal representing a value of a distance from an ablation electrode surface to a target tissue surface, and selecting a value for an operating parameter for supplying energy to an ablation electrode as a function of the first and second signals.

Claim 58 is directed to a method of selecting an operating parameter value for transmitting energy to tissue. The method comprises receiving a first signal representing a value of a fluid flow rate near the tissue, receiving a second signal representing a value of a distance from an ablation electrode surface to a target tissue surface, and selecting a value for an electrode impedance as a function of the first and second signals.

Claim 66 is directed to a method of establishing a relationship between operating condition values and a value for an ablation operating parameter. The method comprises: providing a plurality of data sets comprising a value of fluid flow, a value of impedance, and a value of distance from an ablation electrode surface to a target tissue surface; for each of the plurality of data sets, performing at least two analyses of an ablation electrode transmitting energy to biological tissue using a numerical model, the at least two analyses corresponding to at least two different values of an ablation operating parameter, and wherein the numerical model uses each of the three values of the data set; and based on the results of the at least two analyses for each data set, establishing a relationship between each data set and a corresponding value for the ablation operating parameter.

Claim 87 is directed to a method of establishing a relationship between operating condition values and values for ablation operating parameters. The method comprises

providing a data set comprising values of operating conditions, and performing a first analysis of a numerical model, the numerical model modeling transmission of energy to biological tissue and the first analysis using the values of the operating conditions, a first value for an energy supply operating parameter and a first value for a distance from an ablation electrode surface to a target tissue surface. The method further comprises performing a second analysis of the numerical model using the values of the operating conditions and a second value for the distance from the ablation electrode surface to the target tissue surface. The method further comprises, based on the results of the first and second analyses, establishing a relationship between the data set and corresponding values for the energy supply operating parameter and the distance from the ablation electrode surface to the target tissue surface.

A favorable International Preliminary Report on Patentability in response is requested.

Respectfully submitted,



Eric Amundsen
Reg. No. 46,518
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 646-8000
Facsimile: (617) 646-8646

DOCKET NO. B1075.71016

DATE: 28 January 2005

x 1/28/05

Express Mail Label No.: EL960700835US

PATENT COOPERATION TREATY

IHA

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence
and Administrative Instructions, Section 601(a))

To:
ERIC AMUNDSEN
WOLF, GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MASSACHUSETTS 02210

Date of mailing (day/month/year) **21 APR 2005**

Applicant's or agent's file reference B1075.71016 <i>W000</i>		IMPORTANT NOTIFICATION
International application No. PCT/US2004/009620	International filing date (day/month/year) 29 Mar 2004	Priority date (day/month/year) 28 Mar 2003
Applicant C.R. BARD, INC.		

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

28 Jan 2005

2. That date of receipt is:

- ☒ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).
- ☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
- ☐ the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☐ **ATTENTION:** That date of receipt is after the expiration of 19 months from the priority date. Consequently, in respect of some Offices, the demand does not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)) and the acts for entry into the national phase must therefore be performed within 20 months from the priority date (or later in some Offices). However, in respect of some other Offices, the time limit of 30 months (or later) may nevertheless apply. See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

- ☐ (If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/ Mail Stop PCT, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 703-305-3230	Authorized officer Catherine Williams <i>W</i> Telephone No. 703-308-9290 EX 106
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Form PCT/IPEA/402 (April 2002; reprint January 2004)

Confirmation Docketing	Initials <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="border-bottom: 1px solid black; width: 100%;"></div>
---------------------------	---

dhm

From the INTERNATIONAL BUREAU

PCT

FIRST NOTICE INFORMING THE APPLICANT OF
THE COMMUNICATION OF THE INTERNATIONAL
APPLICATION (TO DESIGNATED OFFICES WHICH
DO NOT APPLY THE 30 MONTH TIME LIMIT
UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

MORRIS, James, H.
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
28 October 2004 (28.10.2004)

Applicant's or agent's file reference
B1075.71016 W.S.

IMPORTANT NOTICE

International application No.
PCT/US2004/009620

International filing date (day/month/year)
29 March 2004 (29.03.2004)

Priority date (day/month/year)
28 March 2003 (28.03.2003)

Applicant

C.R. BARD, INC. et al

- ATTENTION:** For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does apply**, please see Form PCT/IB/308(Second and Supplementary Notice) (to be issued promptly after the expiration of 28 months from the priority date).
- Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93bis.1. The International Bureau has effected that communication on the date indicated below:
14 October 2004 (14.10.2004)

CH

In accordance with Rule 47.1(c-bis)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

- The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93bis.1:

FI, LU, SE, TZ, UG, ZM

In accordance with Rule 47.1(c-bis)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

4. TIME LIMITS for entry into the national phase

For the designated Office(s) listed above, and unless a demand for international preliminary examination has been filed before the expiration of **19 months** from the priority date (see Article 39(1)), the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph**, be **20 MONTHS** from the priority date.

In practice, time limits other than the 20-month time limit will continue to apply, for various periods of time, in respect of certain of the designated Offices listed above. For regular updates on the applicable time limits (20 or 21 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>.

It is the applicant's sole responsibility to monitor all these time limits.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Simin Baharlou

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 71 30